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Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Summary:	October 7, 2013
Contact Person and Address:	Sameer Mansour, Regulatory Affairs Specialist T (901) 399-5579 F (901) 566-7569
Name of Device:	POLARSTEM Standard and Lateral Femoral Stems with Ti/HA
Common Name:	Total Hip Joint, Femoral Component, Cementless
Device Classification Name and Reference:	21 CFR 888.3353 – Hip joint metal/polymer/metal semi-constrained cemented or nonporous uncemented prosthesis 21 CFR 888.3390 – Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis 21 CFR 888.3360 – Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	LZO, KWY, LWJ, MEH

OCT 10 2013

Device Description

The POLARSTEM Standard and Lateral Stems with Ti/HA are similar to the SL-PLUS Standard and Lateral Femoral Stems with Ti/HA cleared via K120211 and the Anthology Hip Stems cleared via K052792. The subject stems are made from forged titanium alloy Ti-6Al-4V with a double coating (triple layer): titanium plasma sprayed coating (two layers) with an additional thin layer of hydroxyapatite.

Intended Use

The POLARSTEM Standard and Lateral Femoral Stems with Ti/HA are intended for advanced degeneration of the hip joint as a result of degenerative, post-traumatic or rheumatoid arthritis; fracture or avascular necrosis of the femoral head; failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement; all forms osteoarthritis; patients with hips at risk of dislocation; femoral neck fracture or proximal fracture to hip joint.

The POLARSTEM Standard and Lateral Femoral Stem with Ti/HA is intended for single use only and is to be implanted without bone cement.

Technological Characteristics

A review of the mechanical data indicates that the POLARSTEM Standard and Lateral Femoral Stems with Ti/HA are capable of withstanding expected *in vivo* loading without failure.

Substantial Equivalence Information

The overall design, materials, and indications for use for the POLARSTEM Standard and Lateral Femoral Stems with Ti/HA are substantially equivalent to the following commercially available predicate devices.

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	SL-PLUS Standard and Lateral Femoral Stems with Ti/HA	K120211	07/19/2012
Smith & Nephew, Inc.	ANTHOLOGY Hip Stems	K052792	10/07/2005
Landos, Inc.	CORAIL Hip Stems	K953111	12/27/1996

The following mechanical tests were used as a basis for the determination of substantial equivalence:

- Stem Fatigue Testing
- Neck Fatigue Testing

All tests which are in relation to the surface characterization (physical, chemical or mechanical) are discussed in detail in the Ti/HA Coating Master File **MAF – 1762**.

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the POLARSTEM Standard and Lateral Femoral Stems with Ti/HA. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to the commercially available predicate devices listed in the table above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 10, 2013

Smith & Nephew, Incorporated
Mr. Sameer Mansour
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K130728
Trade/Device Name: POLARSTEM Standard & Lateral Femoral Stems with Ti/HA
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, KWY, LWJ, MEH
Dated: September 12, 2013
Received: September 13, 2013

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K130728

Device Name: POLARSTEM Standard & Lateral Femoral Stems with Ti/HA

Indications for Use:

The POLARSTEM Standard and Lateral Femoral Stems with Ti/HA are indicated for:

- Advanced degeneration of the hip joint as a result of degenerative, post-traumatic or rheumatoid arthritis.
- Fracture or avascular necrosis of the femoral head
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement
- All forms of osteoarthritis
- Patients with hips at risk of dislocation
- Femoral neck fracture or proximal fracture to hip joint

The POLARSTEM Standard and Lateral Femoral Stem with Ti/HA is intended for single use only and is to be implanted without bone cement.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices